#### IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI NORTHERN DIVISION

RICHARD JORDAN and RICKY CHASE,	) ) )	
Plaintiffs,	)	
THOMAS EDWIN LODEN, Jr.	) ) )	
Intervenor	, )	
v.	Civil Action No	
	) )	
NATHAN "BURL" CAIN, Commissioner,	)	
Mississippi Department of Corrections, in	)	
his Official Capacity; TIMOTHY MORRIS,	)	
Acting Superintendent, Mississippi State	)	
Penitentiary, in his Official Capacity;	)	
THE MISSISSIPPI STATE EXECUTIONER, in his Official Conscitute and UNENOWN	)	
in his Official Capacity; and UNKNOWN EXECUTIONERS, in their Official Capacities,	) )	
Defendants.	, ) <u>)</u>	

# INTERVENOR'S COMPLAINT FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF UNDER THE FEDERAL CIVIL RIGHTS ENFORCEMENT ACT OF 1871 (42 U.S.C. §1983)

#### NATURE OF ACTION

1. This action is brought pursuant to 42 U.S.C. § 1983 and Mississippi law for violations and threatened violations of Intervenor Thomas Edwin Loden, Jr.'s rights to due process and to be free from cruel and unusual punishment under the First, Eighth, and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14, 24, and 28 of the Mississippi Constitution.

- 2. Under the direction of the Defendants named herein, the Mississippi Department of Corrections ("MDOC") intends to execute Mr. Loden with compounded drugs that may be counterfeit, expired, contaminated, and/or sub-potent, creating a substantial risk of serious harm to the Mr. Loden. The decision of the Defendants to use compounded drugs, specifically a compounded anesthetic that has not been tested or approved by the United States Food and Drug Administration ("FDA") and the production of which was not under the supervision or regulation of the FDA, substantially risks that Mr. Loden may be conscious throughout his execution and will experience a torturous death by suffocation and cardiac arrest.
- 3. Further the decision of the Defendants to use compounded pentobarbital as the first drug in a three-drug lethal injection series impermissibly violates the directive of the Mississippi legislature that death sentences be executed by the continuous intravenous administration of "an ultra short-acting barbiturate or other similar drug."
- 4. The entirety of the lethal injection protocol promulgated by MDOC is not at issue in this lawsuit. Rather, this civil action challenges the use of compounded drugs, including but not limited to compounded pentobarbital, in lethal injection executions conducted by MDOC. Further this civil action specifically challenges the use of compounded pentobarbital in a three-drug lethal injection procedure. Lastly this civil action challenges MDOC's intent to have the raw ingredients for pentobarbital compounded into an injectable solution on the grounds of the Mississippi State Penitentiary at Parchman, where there is no pharmacy suitable for compounding sterile drugs. MDOC first ordered compounded drugs for purposes of lethal injection executions on May 20, 2012. That purchase instituted a policy, practice, or custom of using compounded drugs in MDOC executions.

5. Mr. Loden seeks permanent injunctive relief to prevent the Defendants from inflicting cruel and unusual punishment upon him during his execution, and otherwise violating his federal and state constitutional rights. Mr. Loden seeks preliminary injunctive relief to preserve the status quo pending this Court's final adjudication of this civil action.

#### **JURISDICTION AND VENUE**

- 6. Mr. Loden's claims arise under the Constitution and laws of the United States, as well as under the Constitution and laws of the State of Mississippi. This Court has original federal question jurisdiction over those claims arising under the Constitution and laws of the United States pursuant to 28 U.S.C. §§ 1331, 1343. This Court has supplemental jurisdiction over those claims arising under the Constitution and laws of the State of Mississippi pursuant to 28 U.S.C. § 1367(a).
- 7. This Court has the authority to grant declaratory and injunctive relief under 28 U.S.C. § 2201-2202 and FED.R.CIV.P. 57 and 65. The federal rights asserted by Mr. Loden are enforceable under 42 U.S.C. § 1983.
- 8. Venue is proper in the Southern District of Mississippi under 28 U.S.C. §§ 1391(b)(1) and 1391(c)(2). With respect to Section 1391(b)(1), Defendant Marshall Fisher, Commissioner, Mississippi Department of Corrections, in His Official Capacity, is located in Jackson, Hinds County, Mississippi. With respect to Section 1391(c)(2), all Defendants in this action are required to be served with process by service on the Attorney General of Mississippi in Jackson, Hinds County, Mississippi, pursuant to Miss.R.Civ.P. 4(D)(5), incorporated through Fed.R.Civ.P. 4(e)(1).

#### **PARTIES**

- 9. The Intervenor, Thomas Edwin Loden, Jr., is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Thomas Edwin Loden, Jr., filed for relief under the MDOC Administrative Remedy Program on December 15, 2014. The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on January 1, 2015.
- 10. Defendant Marshall L. Fisher is the Commissioner of the Mississippi Department of Corrections.
- 11. The MDOC is the state agency charged with the incarceration, care, custody, and treatment of all state prisoners, including prisoners sentenced to death. Miss. Code Ann. §§ 47-5-10(a); 47-5-23.
- 12. Commissioner Fisher is the chief executive, administrative, and fiscal officer of MDOC, establishes the general policy of MDOC, and oversees the administration of all affairs within MDOC. Miss. Code Ann. §§ 47-5-20(a); 47-5-23; 47-5-24(1).
- 13. As the Commissioner of the MDOC, Mr. Fisher must perform "[a]ll duties and necessary acts pertaining to the execution of a convict . . . except where such duties and actions are vested in the state executioner." Miss. Code Ann. § 99-19-13. *See also* Miss. Code Ann. § 99-19-55.
- 14. Commissioner Fisher is responsible for ensuring that all prisoners committed to the custody of MDOC are treated in accordance with the United States and Mississippi Constitutions.

- 15. At all relevant times, Commissioner Fisher has been acting under the color of law and as the agent and official representative of MDOC, pursuant to MDOC's official policies and procedures. Commissioner Fisher is sued in his official capacity only.
- 16. Defendant Earnest Lee is the Superintendent of the Mississippi State Penitentiary in Parchman, MS, the prison that houses all male death row inmates, and the prison where all executions take place in the State of Mississippi. Miss. Code Ann. § 99-19-55(1).
- 17. Superintendent Lee is responsible for implementing MDOC's policies and procedures governing executions, managing the preparations for an execution, and for turning over the execution site to the State Executioner to perform the execution.
- 18. Superintendent Lee is also responsible for protecting the constitutional rights of all persons incarcerated at the Mississippi State Penitentiary in Parchman, and/or transported to Parchman for an execution.
- 19. At all relevant times, Superintendent Lee has been acting under color of law and as the agent and official representative of the Mississippi State Penitentiary and MDOC. He is sued in his official capacity only.
- 20. The State Executioner of the State of Mississippi is appointed by the Governor and shall supervise and inflict the punishment of death pursuant to Miss. Code Ann. § 99-19-53. The name of the State Executioner is withheld from the public by the State of Mississippi.
- 21. The names of Defendants Unknown Executioners are unknown to Mr. Loden but they include the State Executioner, his or her designee, and members of the State Execution Team. On information and belief, the Unknown Executioners will participate in the process of the execution by virtue of their roles in designing, implementing, carrying out, and/or

supervising the lethal injection process, including the procurement and storage of lethal injection drugs and materials. Miss. Code Ann. § 99-19-53, 99-19-55(2).

22. At all relevant times, Defendants State Executioner and Unknown Executioners have been acting under the color of law. There are sued in their official capacities only.

#### **FACTUAL ALLEGATIONS**

#### A. MISSISSIPPI'S THREE-DRUG LETHAL INJECTION PROTOCOL

- 23. In Mississippi, the manner of execution for individuals sentenced to death is "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.
- 24. MDOC's lethal injection protocol calls for the serial administration of three drugs to put a prisoner to death.
- 25. The first drug, pentobarbital,<sup>1</sup> a short-acting or intermediate-acting barbiturate, is intended to sufficiently anesthetize the prisoner so that he is both unconscious and insensate when the executioner injects the second and third drugs, vecuronium bromide<sup>2</sup> and potassium chloride, respectively.
- 26. Pentobarbital is not "an ultra short-acting barbiturate or other similar drug" as required by Mississippi law.

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<sup>&</sup>lt;sup>1</sup> MDOC's most recent protocol, promulgated in March 2012, calls for the use of Sodium Pentothal as the first drug in the series, but provides for the use of pentobarbital "[i]n the event of an unavailability of a sufficient quantity of sodium pentothal from available sources." As discussed *infra*, Sodium Pentothal is no longer available to MDOC. Sodium Pentothal is the trademarked name for sodium thiopental. The MDOC's execution protocols have never expressly authorized or referenced the use of compounded drugs in executions.

<sup>&</sup>lt;sup>2</sup> The March 2012 protocol calls for the use of pavulon as the second drug in the series, but provides for the use of vecuronium bromide "[i]n the event of unavailability of a sufficient quantity of pavulon from available sources."

- 27. The second drug, vecuronium bromide, is a neuromuscular blocking agent that paralyzes all of the prisoner's voluntary muscles, including the muscles used for respiration, but *does not* suppress sensation, consciousness, cognition, or the ability to feel pain and suffocation. It is used by the MDOC to be the "chemical paralytic agent."
- 28. There is no legitimate penological justification for the use of a neuromuscular blocking agent or other chemical paralytic agent in an execution by lethal injection.
- 29. Neuromuscular blocking agents are not necessary to produce death, and do not diminish the prisoner's awareness or ability to feel pain.
- 30. Over eighty executions have been accomplished in other jurisdictions in the United States without the use of a neuromuscular blocking agent or other chemical paralytic agent. In each of these executions, the prisoner died.
- 31. The only purpose of the neuromuscular blocking agent in Mississippi's lethal injection protocol is to mask the gasping and physical convulsions produced by injection of the final drug, potassium chloride.
- 32. The neuromuscular blocking agent is thus used to make the execution appear serene and peaceful where the State may have in fact failed to sufficiently anesthetize the prisoner against pain and suffering.
- 33. The third and final drug in Mississippi's lethal injection protocol is potassium chloride a chemical that disrupts the electrical signals in the heart, paralyzes the cardiac muscle, and kills the prisoner by cardiac arrest.
- 34. Provided that a lethal dose of the barbiturate is administered, there is no legitimate penological justification for the use of potassium chloride in an execution by lethal injection.

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- 35. Over eighty executions have been accomplished in other jurisdictions in the United States without the use of potassium chloride. In each of these executions, the prisoner died.
- 36. The humaneness and constitutionality of the three-drug lethal injection process hinges on whether the entire dose of the anesthetic (the first drug) is administered correctly, and whether the drug is sufficiently potent, pure, and rapid in onset to ensure that the prisoner is unconscious and insensate so he does not feel the torturous effects of the second and third drugs. If the first drug administered fails to work as intended, the execution will be torturous for the prisoner.

### B. KNOWN RISKS OF THE DRUGS USED IN THE MISSISSIPPI LETHAL INJECTION PROTOCOL

- 37. The drugs used in Mississippi's lethal injection protocol have known and documented risks about which the Defendants are, or should be, aware.
- 38. The first risk is associated with the administration of vecuronium bromide, the drug currently stockpiled by MDOC to serve as the paralytic agent required by the Mississippi statute and protocol.
- 39. Vecuronium bromide causes the paralysis of all voluntary muscles, including the lungs and diaphragm.
- 40. If vecuronium bromide is administered to a prisoner who is still conscious and able to feel pain, he will suffocate to death while experiencing the agonizing and conscious urge to breath.

- 41. Thus, if a prisoner is injected with the paralytic agent vecuronium bromide before he is fully anesthetized and before he is rendered insensate, he will experience conscious paralysis and suffocation.
- 42. However, because the prisoner is completely paralyzed and unable to talk, move, or make facial expressions as a result of being paralyzed, his agony will be completely masked and concealed to observers.
- 43. The second known risk associated with the drugs used in the Mississippi lethal injection protocol is associated with the third and final drug in the series, potassium chloride.
- 44. There is no medical dispute that the injection of potassium chloride into an individual who has not been adequately anesthetized will cause excruciating pain.
- 45. Potassium chloride induces an intense burning sensation throughout the blood vessel walls running through a prisoner's body. If a prisoner is not fully anesthetized prior to the injection of potassium chloride, then he will consciously experience the agony of cardiac arrest.
- 46. The two risks set forth in paragraphs 38 to 45 above create a substantial risk of severe pain and serious harm, particularly where MDOC *will not be* administering an FDA-approved,<sup>3</sup> ultra short-acting barbiturate in sufficient dosage and potency to ensure that the prisoner is completely anesthetized prior to the injection of the paralytic agent and of potassium chloride.
- 47. There is no penological justification for the use of a paralytic agent and potassium chloride in an execution by lethal injection. Executions by lethal injection may be carried out

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<sup>&</sup>lt;sup>3</sup> As used in this Complaint, the term "FDA-approved" includes both the drug itself (i.e. that the drug's formula is approved for distribution to consumers) and the process for manufacturing the drug. An "FDA-approved" drug thus refers to the specific batch or supply of a medication after manufacture.

through the use of a single-drug, anesthetic-only injection, a protocol now used in most executions nationwide and which has proven effective in executing over eighty prisoners to date.

- 48. An execution conducted by MDOC which continues to use a three-drug protocol, thereby refusing to adopt the feasible and readily implemented alternative of a single-drug injection of an FDA-approved, ultra short-acting barbiturate (which significantly reduces the substantial risks of severe pain and serious harm posed by the use of a chemical paralytic agent and potassium chloride), violates the Eighth Amendment.
  - C. RECENT HISTORY OF LETHAL INJECTION EXECUTIONS IN OTHER STATES DEMONSTRATES THE SEVERITY OF THE RISK OF EXTREME PAIN AND TORTURE WHERE THE POTENCY AND DOSAGE OF THE ANESTHETIC IS INSUFFICIENT.
- 49. Reflecting their revulsion against the use of their medications to execute prisoners in the United States, many pharmaceutical manufacturers have ceased production of drugs commonly used in American executions, have refused to sell them to corrections departments that may use them in executions, or have conditioned the sale of such drugs on "end-user agreements" which forbid the resale or use of the drugs for purposes of lethal injection executions.
- 50. Last month, the American Pharmacists Association, the largest association of pharmacists in the United States, voted to adopt a policy which discourages "pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care." Just a week prior to this announcement, the top trade group representing compounding pharmacists in the United States, the International Academy of Compounding Pharmacists, similarly "discourag[ed] its members from participating in the preparation, dispensing, or distribution of compounded medications for use in legally authorized executions."

#### Sodium Thiopental

- 51. Hospira, Inc., the American manufacturer of the anesthetic sodium thiopental, stopped making sodium thiopental in 2011, after the drug's use in executions interfered with Hospira's ability to enter into manufacturing contracts in Europe. Hospira elected to stop making the drug entirely because it could not prevent the drug from getting into the hands of corrections' departments. Although sodium thiopental is manufactured in other countries, the FDA has not approved its importation into the United States.
- 52. Some states including Georgia resorted to violating federal law in order to procure sodium thiopental. Georgia illegally imported the drug from an English pharmaceutical distributor that operated out of the back of a driving school in London.
- 53. In May of 2011, the United States Drug Enforcement Agency ("DEA") seized the illegal sodium thiopental from the Georgia Department of Corrections; however Georgia had already executed two individuals with the illegal substance.
- 54. The compromised drug used in these Georgia executions failed to perform its necessary function of rendering the prisoners unconscious and insensate, causing the two prisoners to experience significant and unnecessary pain and suffering.
- 55. Thus, when Brandon Rhode was executed in September 2010 with the illegally-imported sodium thiopental, his eyes remained open for the entirety of his execution, indicating consciousness during the process.
- 56. Similarly, when Emmanuel Hammond was executed in January 2011 with the illegally-imported sodium thiopental, his eyes also remained open, and he grimaced and appeared to be trying to communicate throughout his execution.

- 57. Mississippi's lethal injection protocol calls for the use of Sodium Pentothal (a trademarked name for sodium thiopental) as the first drug in its series (except in the event of the unavailability of a sufficient quantity of the drug).
- 58. On information and belief, the last execution in Mississippi using Sodium Pentothal as the anesthetic drug given first in the three-drug series was on July 21, 2010. Since that time Mississippi has been unable to legally obtain Sodium Pentothal for use in executions.

#### Nembutal: Pentobarbital Sodium Manufactured by Lundbeck

- 59. Where Sodium Pentothal is unavailable for use as the first drug in the series, the Mississippi execution protocol allows the administration of pentobarbital in its place.
- 60. There is only one manufacturer of FDA-approved injectable pentobarbital sodium, sold under the name-brand Nembutal.
- 61. In July 2011, Lundbeck, the manufacturer of Nembutal, announced that it would no longer sell the drug to departments of corrections, and required purchasers of its drug to enter into end-user agreements by which they agreed not to sell or transfer the drugs to prisons in states that still use capital punishment.
- 62. In December 2011, Lundbeck sold the rights to Nembutal to Akorn, Inc. and, as part of the agreement, Akorn agreed to maintain the restricted distribution program.
- 63. Any Nembutal sold prior to the July 2011 agreement would have expired no later than November 2013.
  - 64. The last time MDOC purchased Nembutal was on March 23, 2011.
  - 65. Any unused drugs from MDOC's purchase of Nembutal have expired.

- 66. By the March 23, 2011 transaction, MDOC purchased 12 units of Nembutal (50 mg/mL). It is unclear from the receiving report disclosed by MDOC what total volume of Nembutal was purchased.
- 67. Upon information and belief, the supply of Nembutal obtained by MDOC in March 2011 was utilized by MDOC in executions conducted in May 2011, and in executions conducted between February and June 2012.<sup>4</sup>
  - 68. The State of Mississippi has not executed any prisoner since June 20, 2012.
- 69. Consequently, Mississippi no longer has any legally-obtained, FDA-approved, and unexpired pentobarbital to use in executions.

#### Experimentation with Anesthetics Previously Not Used in Executions

- 70. Due to this nation-wide shortage of FDA-approved sodium thiopental and pentobarbital for use in executions, some states (including Florida, Ohio, Arizona, and Oklahoma) have executed prisoners with drugs never previously used for lethal injection.
- 71. In Florida, Ohio, and Arizona executions using these experimental drugs caused the prisoners to remain conscious for an unacceptable length of time.
- 72. Since October 2013, Florida has executed prisoners using a three-drug protocol featuring midazolam hydrochloride, a paralytic agent, and potassium chloride. William Happ's execution in Florida the first using this new series took twice the amount of time as prior executions, and he continued to make body movements after he was injected with an untested drug, midazolam hydrochloride.

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<sup>&</sup>lt;sup>4</sup> As discussed *infra*, MDOC did not purchase any additional legally-obtained, FDA-approved, and unexpired pentobarbital after March 2011. Rather in May 2012, MDOC purchased the active pharmaceutical ingredients ("API") to compound pentobarbital. This supply was not received by MDOC until June 13, 2012, according to receiving reports disclosed by MDOC. The State of Mississippi has only conducted one execution – that of Gary Simmons on June 20, 2012 – since this date of receipt. Upon information and belief, MDOC utilized Nembutal still in its possession from the March 2011 purchase in the execution of Mr. Simmons. As such MDOC's current supply of pentobarbital sodium API has never been used in any execution in the state.

- 73. In January 2014, Dennis McGuire's execution in Ohio (using a two-drug injection of midazolam and hydromorphone) took twenty-six (26) minutes, and he gasped for air and gagged throughout the execution signs that he was being suffocated to death.
- 74. The same protocol (midazolam and hydromorphone) was later used in Arizona's execution of Joseph Wood in July 2014, with even more troubling results. Mr. Wood gasped and gulped in the death chamber as prison officials injected 15 doses of lethal injection chemicals into his body for *nearly two hours* before he was pronounced dead.
- 75. Florida's three-drug protocol featuring midazolam hydrochloride was subsequently tried by Oklahoma in April 2014 with torturous results in the botched execution of Clayton Lockett. Mr. Lockett was observed writhing on the execution table and attempting to speak, even after having been declared unconscious.

#### Experimentation with Compounded Drugs

- 76. Some states have responded to the unavailability of Nembutal by turning to the "gray market" of unregulated compounded drugs and unregulated active pharmaceutical ingredients ("API") to obtain compounded pentobarbital for use in executions.
- 77. This type of pharmacy compounding is a deviation from the traditional practice of pharmacy compounding, which involved the mixing of small batches of drugs in response to a physician's prescription to meet the unique needs of an individual patient when an FDA-approved drug is not suitable for the patient.
- 78. Compounded drugs are not FDA-approved and have not been evaluated for effectiveness and safety. Until recently, the FDA did not regulate compounded drugs and compounding pharmacies at all, and even now, the FDA does not have regulatory authority over all compounding pharmacies.

- 79. Compounded drugs are created without producing the data on safety and efficacy that the FDA requires for new drugs, and without the requirement that they follow good manufacturing practice regulations (GMPs) which insure their identity, strength, quality and purity. Thus the FDA has noted "quality problems with various compounded drugs, including sub-potency, super-potency, and contamination."
- 80. State regulation of compounding pharmacies varies substantially, but no state regulates compounding pharmacies in a manner that would replicate the FDA's regulation of pharmaceutical manufacturers. Without unified standards and regulations there is no way to guarantee that drugs from a compounding pharmacy are what they purport to be and are safe and effective.
- 81. In recent years, a substandard compounding drug industry has emerged wherein compounding pharmacies create and market copies of FDA-approved drugs for general distribution. These drugs are developed and sold without the testing required by the FDA to ensure that the drugs are potent, pure, safe, and effective.
- 82. Additionally, there is a significant risk that compounded drugs are manufactured with counterfeit or substandard ingredients purchased from a range of manufacturers that operate outside of FDA supervision and regulation.
- 83. For these reasons, among others, the FDA has called the proliferation of compounded drugs a "troubling trend" because it has resulted in individuals taking harmful, contaminated, counterfeit, sub-potent, and/or super-potent drugs.
- 84. This is not a speculative risk. The 2012 outbreak of fungal meningitis caused by contaminated steroid injections from a compounding pharmacy in New England drew national attention to the regulatory vacuum within which compounding pharmacies operate, and the

substandard and harmful products that these pharmacies can market to the public. Two senior executives of the New England pharmacy have since been indicted on charges of racketeering and murder. The compounded drugs responsible for the meningitis outbreak had been "tested" and found potent by a laboratory purporting to be "independent."

- 85. Further, Oklahoma executed Michael Lee Wilson with compounded pentobarbital on January 9, 2014. After Mr. Wilson spoke his final words, and after the executioner administered the first drug, Mr. Wilson spoke again and stated: "I feel my whole body burning."
- 86. The burning sensation relayed by Mr. Wilson during his execution is consistent with an excruciatingly painful reaction to the injection of contaminated pentobarbital.

### D. MISSISSIPPI'S DECISION TO USE COMPOUNDED DRUGS IN LETHAL INJECTION EXECUTIONS

- 87. Because MDOC can no longer obtain the FDA-approved form of pentobarbital, the Defendants, jointly and/or severally, have obtained pentobarbital sodium API for use in lethal injections from a compounding pharmacy in Grenada, Mississippi that otherwise markets its expertise in herbal supplements.
- 88. On or around May 20, 2012, MDOC purchased \$3,150 worth of pentobarbital sodium from H&W Compounding Pharmacy d/b/a Brister Brothers ("Brister Brothers"), a compounding pharmacy in Grenada, MS. According to a receiving report disclosed by MDOC, this supply was received by the Department on June 13, 2012.<sup>5</sup> Brister Brothers purchased the pentobarbital sodium API from Professional Compounding Centers of America, Inc. ("PCCA"), in Houston, Texas.

<sup>&</sup>lt;sup>5</sup> MDOC also purchased vecuronium bromide and potassium chloride from the Brister Brothers pharmacy but this supply expired in 2014 and has since been destroyed. MDOC has subsequently purchased new supplies of vecuronium bromide and potassium chloride (reported to expire in fall 2015). MDOC refuses to disclose the provider of its current supply of vecuronium bromide and potassium chloride. This failure to disclose the identity of lethal injection drug suppliers is the subject of ongoing litigation between the MacArthur Justice Center and MDOC under the Mississippi Public Records Act. A chancery court has ordered the disclosure of the identity of the drug supplier but MDOC has appealed this ruling to the Mississippi Supreme Court.

- 89. Upon information and belief, Defendants did not purchase Nembutal or another sterile, injectable pentobarbital from Brister Brothers on or around May, 20, 2012 or at any time thereafter.
- 90. Specifically Defendants purchased 70 grams of raw materials or active pharmaceutical ingredients ("API") from Brister Brothers.
- 91. Upon information and belief, these 70 grams were packaged as 14 vials containing 5 grams each.
- 92. Defendants have not purchased any additional pentobarbital sodium API since May 20, 2012. Of the 14 vials purchased on this date, MDOC only has nine (9) vials remaining in its custody.
- 93. The 70 grams of pentobarbital sodium API which Defendants purchased from Brister Brothers were not compounded prior to the shipment from Brister Brothers to the grounds of the Mississippi State Penitentiary at Parchman. Thus, the pentobarbital will have to be compounded before its use in any execution in Mississippi.
- 94. According to the records of the Mississippi State Board of Pharmacy, there is no registered or licensed pharmacy at the Medical/Dental Facility at Parchman (Mississippi State Department of Health License No. 11-317). Drugs administered to prisoners are kept in the Drug Room at the Medical/Dental Facility at Parchman.
- 95. According to the MDOC's Chemical Supply Inventory, drugs used for lethal injection are not kept in the Drug Room, but at Unit 17, the building where death-sentenced prisoners were once incarcerated, and which is now used exclusively to house a condemned prisoner the days before his scheduled execution and to house the death chamber where he will

be executed. The nine (9) vials of pentobarbital sodium API in MDOC's possession is set to expire on May 20, 2015.

- 96. Upon information and belief, MDOC has never used this supply of pentobarbital sodium API in an execution.
- 97. Upon information and belief, Defendants have not yet compounded the raw pentobarbital. There is no public record of MDOC sending the raw pentobarbital to a compounding pharmacy. Additionally, an affidavit executed by Special Assistant Attorney General Jim Norris on March 10, 2014 describes the pentobarbital sodium as being in a "powder" form.
- 98. Upon information and belief, the Defendants intend to compound the pentobarbital on the grounds of the Mississippi State Penitentiary at Parchman; or in the alternative, the Defendants intend to send the raw pentobarbital to a yet undisclosed location to prepare the drug for an execution.
- 99. If Mississippi proceeds with their executions, Mr. Loden will be among the first prisoners in Mississippi to be executed with compound pentobarbital.

### E. CONSTITUTIONAL, PHARMACEUTICAL, AND MEDICAL RISKS PRESENTED BY DEFENDANTS' USE OF COMPOUNDED PENTOBARBITAL

- 100. Because Mississippi will use a three-drug formula in its executions, the humaneness and the constitutionality of the procedure depends entirely on the first drug working as intended and deeply anesthetizing the prisoner.
- 101. When compounded pentobarbital is used as the first drug in the three-drug formula, risks are introduced to the execution procedure which serve no valid penological purpose. Compounded drugs are not FDA-approved, so they carry no guarantees of the identity, purity, or potency of the drug.

- 102. Compounding pharmacies such as Brister Brothers generally do not have the facilities to test chemicals for identity, potency, purity, and contamination.
- 103. It is not possible for testing of API to eliminate the risks posed by impurities, contaminants, particulate matter, and/or an improper pH balance. Testing only provides a very provisional indication of an API's suitability for compounding given the unknowns about the chemical's integrity, storage, and custody in the timeframe from testing to pharmacy compounding and use.
- 104. Testing of non-sterile API by laboratories contracting with a distributor has proven unreliable. Poorly regulated, if regulated at all, contract-testing laboratories are supposed to test compounded drugs for safety and effectiveness. Too often, however, these laboratories are themselves substandard, and many are established to serve the financial interests of the pharmacies for which they are doing the testing. Five laboratories that test compounded drugs have had enforcement actions taken against them by the FDA.
- 105. Where the compounded pentobarbital is in any way sub-optimal, it poses a substantial risk of serious harm to the condemned prisoner either by inflicting pain and suffering itself or by failing to adequately anesthetize the prisoner, who then would experience conscious paralysis and the pain of potassium chloride, followed by cardiac arrest.
- 106. Moreover, each injection of compounded pentobarbital used in executions in Mississippi will be a new product, so the effectiveness of one dose does not demonstrate the effectiveness of the next.

#### The Questionable Integrity of the Materials in the Possession of the Defendants

107. The integrity of the MDOC's supply of sodium pentobarbital API has not been verified, and these ingredients could very well be counterfeit, contaminated, or substandard.

- 108. The Defendants have not revealed the source of the active pharmaceutical ingredients that were used or will be used to make the compounded drug.
- 109. PCCA's source for the pentobarbital sodium API is not a matter of public record and is unknown to Mr. Loden.
- 110. On information and belief, Defendants themselves do not know the source of the pentobarbital sodium API sold by PCCA to Brister Brothers, and from Brister Brothers to MDOC.
- 111. PCCA expressly disclaimed any warranties in its sale of pentobarbital sodium API to Brister Brothers.

#### The Questionable Process for the Compounding of Mississippi's Execution Drugs

- 112. The Defendants refusal to disclose critical facts surrounding the compounding process is also problematic.
- 113. In order to properly and safely compound the raw ingredients for pentobarbital into a sterile injectable, the compounding must be done in a sterile compounding laboratory with very specific and sophisticated physical requirements.
- 114. Under State law, a pharmacy or medical facility must be registered with the Mississippi State Board of Pharmacy in order to manufacture pentobarbital or another controlled substance. The pharmacy or facility cannot manufacture any controlled substance not authorized by its registration. Miss. Code Ann. §41-29-125, 41-29-141(2). Manufacture, in this context, includes compounding. Miss. Code Ann. §41-29-105(q).
- 115. As stated above, the State Board of Pharmacy does not list the Medical/Dental Facility at Parchman as a facility with a licensed pharmacy. The State Board of Pharmacy does

not list the Medical/Dental Facility at Parchman as a facility registered to compound controlled substances.

- 116. There are a limited number of compounding laboratories in Mississippi, and MDOC has not revealed to Mr. Loden where or how they intend to compound the raw pentobarbital.
- 117. The compounding of sodium pentobarbital API or any other drug on the grounds of the Mississippi State Penitentiary creates substantial risks that a drug so manufactured may be contaminated during compounding, and/or the compounding process may be flawed, resulting in the production of a sub-potent and ineffective drug.

#### The Risk That the Pentobarbital Is Degraded or Expired

- 118. The expiration dates for FDA-approved drugs are based on rigorous testing in a controlled and regulated environment. The same testing is not performed on compounded drugs, resulting in an unacceptable risk that the drug may be degraded and sub-potent by the time it is used, and unable to perform its designated anesthetic function.
- 119. According to the March 10, 2014 affidavit of MDOC attorney Jim Norris and records from PCCA, the batch of pentobarbital sodium API held by MDOC has an expiration date of May 20, 2015. The risk of sub-potency and/or degradation of the API (and ultimately of any pentobarbital compounded therefrom) is greatly increased when a drug has passed its expiration date.
- 120. Even a small level of contamination or small deviation in the preparation process will, over time, lead to increasing deterioration of the quality of the batch. Because the MDOC's batch of pentobarbital is at the brink of its expiration date, a small problem with the initial preparation may well have progressed, over time, into a severe problem that will cause an

anomaly or botch. Any contamination, sub-potency, or super-potency in the original preparation may be enhanced as the batch ages closer to its expiration date.

121. Other records provided by MDOC indicate that the vecuronium bromide possessed by the Defendants will expire on October 1, 2015, and the potassium chloride possessed by the Defendants will expire on September 1, 2015.

#### The Risk of Counterfeit API

- 122. One of the purposes of FDA regulation is to ensure that the drugs and narcotics used by Americans are true and genuine. The risk of counterfeit or "watered-down" drugs is a substantial part of the FDA's justification for prohibiting Americans from purchasing narcotics and drugs from foreign pharmacies or sources.
- 123. Because Defendants have not procured the drugs for lethal injections from an FDA-approved source, there is a risk that the materials which Defendants claim to be pentobarbital, vecuronium bromide, and potassium chloride are, in fact, nothing of the sort. The materials in Defendants' possession may be "watered-down" or wholly counterfeit.

#### Compounded Pentobarbital Is Not an Ultra Short-Acting Barbiturate

124. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

- 125. Unable to obtain Sodium Pentothal or Nembutal, MDOC has now purchased pentobarbital sodium API to be compounded into an injectable solution to be used as the first drug in the three-drug series.
- 126. Compounded pentobarbital *is not* an ultra short-acting barbiturate like Sodium Pentothal. Rather pentobarbital is classified as a short- or intermediate-acting barbiturate.
- 127. This classification system refers to the rate of onset and length of duration for a given class of barbiturates. Those barbiturates classified as ultra short-acting have the fastest rate of onset, producing their anesthetic effect more quickly than all other classes of barbiturates. By contrast, short- or intermediate-acting barbiturates have a slower rate of onset than those barbiturates classified as ultra short-acting, taking longer to produce any anesthetic effect upon injection.
- 128. As there is substantial risk that compounded pentobarbital may be sub-potent, the onset rate of compounded pentobarbital would be even slower than that of FDA-approved pentobarbital.
- 129. An understanding of this classification system is of the utmost importance when a barbiturate is planned for use as the first drug in three-drug protocol for execution by lethal injection. Where the first drug does not act swiftly and effectively to anesthetize the prisoner such that he is both unconscious and insensate *before* the executioner injects the second and third drugs, there is a substantial risk of severe pain and suffering.
- 130. It was with this understanding in mind that the Mississippi legislature specifically directed the use of an ultra short-acting barbiturate for use in lethal injections. Furthermore any chemical which does not mirror the ultra short-acting property of the drug class explicitly prescribed for use by the statute cannot be considered an "other similar drug."

- 131. The current MDOC execution protocol does not account for the difference between an ultra short-acting barbiturate and other classes of barbiturates. The protocol simply substitutes pentobarbital for Sodium Pentothal with no other changes to the procedure.
- 132. According to execution logs produced by MDOC, the intervals between the administration of the anesthetic and paralytic drugs have not been lengthened as a result of substituting pentobarbital for the ultra short-acting barbiturate required by the Mississippi statute.

#### Summary of Risks Presented by Defendants' Conduct

- 133. For the reasons set forth above, there is a high risk that either: (a) the Defendants intend to use a degraded form of compounded pentobarbital for the execution of Mr. Loden; (b) the Defendants have obtained only the raw ingredients for pentobarbital and intend to compound the pentobarbital at the Mississippi State Penitentiary; or (c) the Defendants have devised some other unknown and heretofore untested method of making pentobarbital.
- 134. The administration of pure and potent pentobarbital is the crucial step in the execution process to ensure that a condemned prisoner does not consciously experience the agonizing pain of live suffocation and cardiac arrest.
- 135. Defendants' decision to use a non-FDA-approved form of pentobarbital made with unknown and potentially contaminated or counterfeit ingredients is nothing short of human experimentation and presents an unacceptable risk that Plaintiffs will experience unnecessary pain and suffering if and when they are executed.
- 136. Defendants' decision to use a new and experimental lethal injection protocol without adequate assurances that the pentobarbital is manufactured according to accepted pharmaceutical practices and with pure and potent ingredients presents an unacceptable risk that

MDOC will attempt to execute Mr. Loden with an expired, contaminated, degraded, or subpotent form of pentobarbital, resulting in the infliction of cruel and unusual punishment.

#### Defendant's Policy of Secrecy

- 137. On November 20, 2014 and February 20, 2015, the MacArthur Justice Center submitted public records requests to MDOC pursuant to Miss. Code Ann. § 25-65-1 et seq., wherein counsel for Plaintiffs Jordan and Chase requested documents and correspondence pertaining to MDOC's lethal injection protocol, and where and how MDOC procured its lethal injection drugs.<sup>6</sup>
- 138. In response to the November 20 request, MDOC provided 10-pages of heavily-redacted documents, stating that MDOC would not disclose any information that could identify the supplier or manufacturer of their lethal injection drugs out of fear that such disclosure of public information would negatively affect MDOC's supply of such drugs.
- 139. MDOC's failure to comply with the Mississippi Public Records Act and disclose public records related to their supply of lethal injection drugs is currently the subject of litigation between the MacArthur Justice Center and MDOC. The trial court has ruled in favor of the MacArthur Justice Center, ordering MDOC to provide un-redacted records as to their purchase of lethal injection drugs, awarding attorneys' fees, costs, and expenses, and denying a stay of this ruling pending appeal. MDOC has filed for appeal with the Mississippi Supreme Court.

<sup>&</sup>lt;sup>6</sup> The MacArthur Justice Center had submitted another request to MDOC on February 7, 2014, similarly requesting public documents pertaining to MDOC's lethal injection protocol and lethal injection drugs. After receiving records redacted for the identity of the supplier of MDOC's lethal injection drugs, the MacArthur Justice Center filed suit against MDOC for violations of the Mississippi Public Records Act (filed March 3, 2014). This lawsuit was ultimately mooted when the MacArthur Justice Center was able to determine the identity of MDOC's lethal injection drug supplier – the Brister Brothers – through information make publically-available by the MDOC on the state's Transparency website (as operated by the Department of Finance and Administration pursuant to the Mississippi Accountability and Transparency Act of 2008).

- 140. In response to the February 20 request, MDOC has again provided redacted records, claiming the ongoing litigation between the MacArthur Justice Center and MDOC as the basis for the denial.
- 141. Importantly, in the records provided on April 14, 2015, in response to the February 20 request, MDOC has redacted *even more* information from records which have previously been made available to the MacArthur Justice Center. Specifically, MDOC has redacted the month from records as to the date of purchase of the pentobarbital sodium API, and has provided records of the six (6) executions carried out by Mississippi in 2012 in response to an inquiry about the disposition of five (5) vials of the pentobarbital sodium API that have left the possession of the MDOC since June 2012.
- 142. By these calculated redactions of documents produced in response to a specific request for information about the use, disposal, or transfer of MDOC's pentobarbital sodium API, MDOC seeks to mislead the public to believe that the pentobarbital sodium API which has left MDOC's possession was used in the executions the state conducted in 2012. This is impossible given the fact known through records MDOC previously disclosed that the API was not in MDOC's possession until *after* five (5) of the six (6) executions carried out in 2012 had already occurred.<sup>7</sup>
- 143. The MacArthur Justice Center was previously able to identify the supplier of MDOC's lethal injection drugs through its own investigation, *see* footnote 6 *supra*, but MDOC has since purchased new vecuronium bromide and potassium chloride (the second and third drugs in the execution series), and the identity of the supplier of these drugs is unknown. MDOC

<sup>&</sup>lt;sup>7</sup> The April 13, 2015 MDOC Public Records Act response was also inconsistent with the statement of counsel for the MDOC in a March 2, 2015 hearing in the chancery court case brought by the MacArthur Justice Center against MDOC, see footnote 5. Counsel asserted then that the unaccounted for pentobarbital sodium API had been destroyed because it had passed its expiration date. All documents produced by MDOC, however, demonstrated that all of the sodium pentobarbital API purchased from Brister Brothers had the same expiration date – May 20, 2015.

maintains a policy of secrecy with regard to where and from whom they purchase lethal injection drugs, and how and where those drugs are prepared for use in executions.

- 144. States continue to have difficulty purchasing pentobarbital in any form. Consequently, Defendants may change their protocol or purchase different drugs or active pharmaceutical ingredients from different manufacturers before the next scheduled execution.
  - 145. No execution is currently scheduled in the State of Mississippi.
- 146. Upon information and belief, Defendants have not compounded the pentobarbital sodium API into a sterile injectable form, and if Mr. Loden is scheduled for an execution before the May 20, 2015 expiration date, his execution will be the first in which Defendants use this compounded pentobarbital.
- 147. Defendants have failed to disclose any information as to their ability to or history of successfully compounding the pentobarbital sodium API in their possession into a sterile injectable form for use in executions. Defendants have also failed to disclose what information, if any, they have researched, gathered, or relied upon to evaluate the efficacy or effect of this new drug when used for an execution.
- 148. Defendants' failure to disclose the manufacturer of the active pharmaceutical ingredients deprives Mr. Loden of any means to assess the purity of the API from which the injectable form of pentobarbital has or will be made; whether the API has been diluted with any substances which could impact the potency of the final product; whether the API is contaminated with either particulate foreign matter or a microbial biohazard that could lead to a severe allergic or neurotoxic reaction upon injection and several other similar issues.
- 149. Defendants will not disclose to Mr. Loden where and when they plan to compound the drug, or the training and qualifications of the individuals who will participate in

and supervise the compounding process. Mr. Loden has no way to assess the qualifications of the compounding pharmacy, whether the facility is actually equipped to make sterile injectable drugs such as pentobarbital, or whether the facilities are equipped to conduct any testing on the identity and/or purity of the API.

150. Defendants' policy of secrecy, and their failure to disclose the manufacturer of the API it purchased from Brister Brothers, and where, how, and when they intend to try to compound the API into a sterile injectable form of pentobarbital violates Mr. Loden's right to be free from cruel and unusual punishment, to due process, and to access to the courts.

#### **CLAIMS FOR RELIEF**

Count I: Use of Compounded Pentobarbital in a Three-Drug Lethal Injection Protocol Violates Intervenor's Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

- 151. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 150.
- 152. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is among the ultra short-acting barbiturates authorized by the Mississippi lethal injection statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 153. Defendants also no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of the Mississippi statute.
- 154. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Mr. Loden's right to be free from cruel and unusual punishment and to due

process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claim II *infra*.

- 155. Defendants plan to use a compounded form of pentobarbital made from active pharmaceutical ingredients of unknown origin that may be counterfeit, contaminated, or ineffective.
- 156. In the alternative, Defendants intend to compound the drug by some other means pursuant to an unknown process and protocol, and by individuals with unknown qualifications.
- 157. The Eighth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, and the corresponding provisions of the Mississippi Constitution, prohibit the infliction of unnecessary pain in the execution of a death sentence.
- 158. Because it is nearly impossible to determine with certainty whether a prisoner will suffer serious and needless pain and suffering during an execution, the question of whether a particular execution procedure will inflict such pain and suffering involves an inquiry as to whether the prisoner is subject to a substantial or intolerable risk of serious harm.
- 159. Such a substantial or intolerable risk of serious harm may occur when a state lacks a clear protocol for lethal injection, when experience with the procedure demonstrates that there are foreseeable problems, or when it is known that the drugs intended for use in lethal injections will very likely result in the prisoner suffering intense pain that an alternative procedure would not cause.
- 160. The Defendants' decision to use a previously untried form of pentobarbital created with unknown and unregulated ingredients through an unknown and unregulated compounding process creates a substantial and intolerable risk that the pentobarbital will be

counterfeit, contaminated, degraded, expired, or sub-potent, resulting in the infliction of cruel and unusual punishment.

- 161. The Defendants' untried and untested drugs create a substantial risk that Plaintiffs will suffer unnecessary and excruciating pain either by the injection of the compounded pentobarbital causing a painful reaction itself, or by the compounded pentobarbital failing to work, resulting in a torturous death by life suffocation and cardiac arrest.
- 162. Thus, Mississippi's planned use of compounded pentobarbital as the first drug in a three-drug series, which is completed with the intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to Thomas Edwin Loden Jr.
- 163. There is a feasible alternative which could substantially reduce the risk of severe pain and serious harm presented by the continuous intravenous administration of compounded pentobarbital in combination with a chemical paralytic agent and potassium chloride.
- 164. The use of an FDA-approved, ultra short-acting barbiturate in a single-drug protocol is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure. Other jurisdictions have already moved towards the use of a single-drug anesthetic-only protocol.
- 165. Defendants' refusal to adopt this alternative for the execution of Thomas Edwin Loden, Jr., in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of execution, constitutes cruel and unusual punishment prohibited by the Eighth Amendment.
- 166. To the extent that Defendants' refusal to adopt the single-drug anesthetic-only barbiturate technique is based on the requirements of Miss. Code Ann. §99-19-51, that part of the

statute which requires the use of a "chemical paralytic agent" in executions should be held unconstitutional as contrary to the Eighth Amendment.

- 167. For the reasons set forth above, Defendants are deliberately indifferent to Mr. Loden's constitutional rights.
- 168. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count I.

Count II: Failure to Use an Ultra Short-Acting Barbiturate or Other Similar Drug as Directed by Mississippi Statute Violates Intervenor's Right to be Free from Cruel and Unusual Punishment and Right to Due Process under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

- 169. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 168.
- 170. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.
- 171. Intervenor, Thomas Edwin Loden, Jr. has a liberty interest created by the requirement of an "ultra short-acting barbiturate or other similar drug" in Section 99-19-51. This interest is protected from arbitrary deprivation by the Due Process Clause of the Fourteenth Amendment.

- 172. Prior to 2011, Defendants used Sodium Pentothal (also known as sodium thiopental) as the first drug in a three-drug lethal injection protocol. Sodium Pentothal is classified as an ultra short-acting barbiturate. This classification is based on the drug's speed of onset and duration of effect. Use of an ultra short-acting barbiturate in Mississippi's execution protocol is necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs.
- 173. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. As a result, MDOC has amended its protocol to allow for the use of pentobarbital as the first drug in the three-drug series where Sodium Pentothal is unavailable.
- 174. Pentobarbital even in its FDA-approved form is never classified as an ultra short-acting barbiturate. Rather it is classified as a short- or intermediate-acting barbiturate. This classification recognizes the slower speed of onset of pentobarbital when compared to an ultra short-acting barbiturate.
- 175. While the Mississippi statute provides for use of an "ultra short-acting barbiturate or other similar drug," pentobarbital is not sufficiently similar to an ultra short-acting barbiturate as to be considered an "other similar drug" within the meaning of a statute. This is true even for FDA-approved pentobarbital, let alone for compounded pentobarbital made from unknown active pharmaceutical ingredients, as MDOC intends to now use.
- 176. MDOC's decision to use compounded pentobarbital as the first drug in its upcoming executions is in clear violation of Miss. Code Ann. § 99-19-51. As such this decision violates Mr. Loden's right, guaranteed by the Eighth Amendment to the United States Constitution and Article 3, Section 28 of the Mississippi Constitution, be free from cruel and unusual punishment.

- 177. MDOC's decision to use compounded pentobarbital as the first drug in its upcoming executions further violates Mr. Loden's right, guaranteed by the Fourteenth Amendment to the United States Constitution and Article 3, Section 14 of the Mississippi Constitution, to not be executed except in accordance with Section 99-19-51. Mississippi law provides no adequate post-deprivation remedy for the harm that will be caused by Defendants' denial of Mr. Loden's right to be executed only with the use of an ultra short-acting barbiturate.
- 178. For the reasons set forth above, MDOC's failure to use an ultra short-acting barbiturate as required by Miss. Code Ann. §99-19-51 creates an unacceptable risk of severe pain and serious harm in violation of the Eighth Amendment.
- 179. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count II.
- Count III: Mississippi's Continued Use of a Three-Drug Protocol in the Face of Evolving Standards of Decency Which Require Abandonment of the Use of a Chemical Paralytic Agent and Potassium Chloride, Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution
- 180. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 180.
- 181. "The basic concept underlying the Eighth Amendment is nothing less than the dignity of man . . . . The Amendment must draw its meaning from the evolving standards of decency that mark the progress of a maturing society." *Atkins v. Virginia*, 536 U.S. 304, 311-312 (2002) (quoting Trop v. Dulles, 356 U.S. 86 (1958)). The United States Supreme Court has repeatedly looked to legislation enacted by the states as the "clearest and most reliable objective evidence of contemporary values," *id.* at 312 (*quoting Penry v. Lynaugh*, 492 U.S. 302, 331

(1989)), relying on such legislative evidence of evolving trends to narrow the classes of those individuals we seek to punish through the death penalty and to determine the suitability of those methods and protocols by which we carry out such sentences.

- 182. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Defendants have not used Sodium Pentothal in an execution since 2010.
- 183. Defendants have amended their lethal injection protocol to provide for the use of pentobarbital in the event that Sodium Pentothal is unavailable. In executions conducted in 2011 and in 2012, MDOC used pentobarbital as the first drug in its three-drug lethal injection protocol, in place of Sodium Pentothal.
- 184. On information and belief, all eight (8) of these executions used the FDA-approved form of pentobarbital, marked as Nembutal and purchased by MDOC in March 2011.
- 185. Defendants no longer possess an FDA-approved form of pentobarbital. Instead Defendants have purchased pentobarbital sodium API to be compounded into injectable pentobarbital for use in upcoming lethal injections.
- 186. Mississippi's decision to continue use of a three-drug lethal injection protocol, particularly one employing pentobarbital, runs contrary to the trend towards single-drug, anesthetic-only protocols employed successfully by other states in recent years.
- 187. All other states which have conducted executions in 2014 and 2015 have completely abandoned the use of pentobarbital (compounded or otherwise) in a multi-drug lethal injection protocol. No state has used pentobarbital in a three-drug protocol this year (with 13 executions having been conducted by five states to date). Only Oklahoma used pentobarbital in a three-drug protocol in 2014, accounting for just two (2) of the 35 executions conducted by seven (7) states last year.

- 188. Furthermore Oklahoma itself has since moved away from the use of pentobarbital in its three-drug series, for while the state conducted two executions with pentobarbital in January 2014, Oklahoma conducted its third execution in 2014 using an alternate drug as the first drug in its three-drug series.<sup>8</sup>
- 189. The chart below summarizes this evolving trend away from the use of three-drug lethal injection protocols, particularly those involving pentobarbital. The execution methods, protocols, and drugs (as contained in the chart) track the lethal injection statutes propagated by state legislatures, as well as the lethal injection protocols propagated and implemented by state departments of corrections.

	3-drug sodium thiopental	1-drug sodium thiopental	3-drug pentobarbital	1-drug pentobarbit al	3-drug midazolam	2-drug midazolam	Other	Total
2010	34	9	1	0	0	0	2	46
	TX, LA, OK, FL, MS, VA, AL, GA, AZ	OH, WA	OK				VA, UT	
2011	7	1	31	4	0	0	0	43
	AL, GA, MO, TX, AZ	ОН	OK, TX, SC, MS, AL, AZ, GA, DE, VA, FL, ID	ОН				
2012	0	0	OK, TX, MS, FL, DE	AZ, OH, ID, TX, SD	0	0	0	43
2013	0	0	12	24	2	0	1	39
			OK, FL, AL	TX, GA, OH, AZ, MO	FL		VA	
2014	0	0	2	22	9	2		35
			OK	TX, MO, GA	FL, OK	OH, AZ		
2015	0	0	0	11	2	0	0	13 (to date)
				GA, TX, MO	FL, OK			,,

<sup>&</sup>lt;sup>8</sup> Oklahoma executed Clayton Lockett on April 29, 2014 using a three-drug series of midazolam hydrochloride, followed by a paralytic agent and potassium chloride. This botched execution further documented the substantial risk of serious harm posed by the use of a three-drug protocol. The lethal injection protocol implemented by Oklahoma in September of 2014 provides for four (4) different lethal injection procedures, but does not include a three-drug series featuring pentobarbital as one of these procedures.

- 190. The trend towards abandonment of the three-drug protocol is evidence of the evolving standards of decency which inform the Eighth Amendment. From 2010 to 2012, of the 132 executions conducted nationwide, over 70 percent (94 executions) were conducted using a three-drug protocol. Yet since 2013, just three states have conducted executions using a three-drug protocol, a total of 27 executions (31 percent) of the 87 conducted nationwide. Only 14 of these 87 executions used pentobarbital in a three-drug series (16 percent of executions nationwide).
- 191. Put another way, forty-seven of the fifty states punish murder without undertaking the risk of conscious, torturous pain and suffocation which is raised by the use of a chemical paralytic agent and potassium chloride in the three-drug protocol.
- 192. It follows that use of the three-drug protocol by Mississippi constitutes cruel and unusual punishment in violation of the Eighth Amendment.
- 193. Defendants continued use of a pentobarbital-based three-drug lethal injection protocol, when other states have abandoned this method in favor of a single-drug, anesthetic-only protocol, violates Mr. Loden's right to be free from cruel and unusual punishment as guaranteed by the United States and Mississippi Constitutions.
- 194. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count III.

## Count IV: Violation of Intervenor's Right to Notice of the Defendants' Method of Execution under the Fourteenth Amendment to the United States Constitution and Article 3, Section 14 of the Mississippi Constitution

195. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 194.

- 196. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 197. Defendants also no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of Mississippi statute. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Plaintiffs' rights to be free from cruel and unusual punishment and to due process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claims *supra*.
- 198. Defendants have obtained active pharmaceutical ingredients from a compounding pharmacy to try to manufacture a sterile injectable form of pentobarbital.
- 199. Defendants have not disclosed where they have compounded, or where they intend to compound the raw ingredients to try to make a sterile injectable form of pentobarbital.
- 200. Defendants have not disclosed the training or qualifications of the individuals responsible for trying to compound the raw ingredients to make a sterile injectable form of pentobarbital.
- 201. Upon information and belief, Defendants intend to execute Mr. Loden with drugs or ingredients that have never been used before in an execution in Mississippi.
- 202. Under the due process clauses of the United States and Mississippi Constitutions, Mr. Loden is entitled to notice of the Defendants' intended method of execution, including information about the drugs Defendants have obtained and the steps by which these API will be compounded into a sterile injection to be used in executions.

- 203. Defendants' failure to disclose the manufacturer of the active pharmaceutical ingredients it purchased to make pentobarbital, and Defendants' failure to disclose how, where, and when they intend to try to compound the raw ingredients into a sterile injectable form of pentobarbital violates Mr. Loden's right to due process under the United States and Mississippi Constitutions.
- 204. For the reasons set forth above, Defendants are deliberately indifferent to Mr. Loden's constitutional rights.
- 205. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count IV.

## Count V: Violation of Intervenor's Right of Access to the Courts under the First and Fourteenth Amendment to the United States Constitution and Article 3, Section 14 and 24 of the Mississippi Constitution

- 206. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 205.
- 207. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 208. Defendants also no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of Mississippi statute. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Plaintiffs' rights to be free

from cruel and unusual punishment and to due process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claims *supra*.

- 209. Due to the unavailability of FDA-approved pentobarbital, Defendants have changed their lethal injection protocol by substituting a compounded form of pentobarbital for the FDA-approved drug Nembutal.
- 210. Defendants have purchased the active pharmaceutical ingredients for pentobarbital, and already have, or will in the future, devise a way to try to compound the active pharmaceutical ingredients to create a sterile injectable form of pentobarbital.
- 211. Defendants have asserted that the identity of the manufacturer and supplier of lethal injection drugs is confidential for fear the disclosure of such information would forestall MDOC's ability to obtain lethal injection drugs in the future. MDOC will not tell MacArthur Justice Center or Intervenor who manufactured the active pharmaceutical ingredients, where the drugs have been or will be compounded, and the training and qualifications of the individuals who have or will compound the drugs. This information is necessary in order for Mr. Loden to more fully determine the risks associated with Defendants' lethal injection drugs.
- 212. Mr. Loden possesses a right to file a legal challenge to enjoin their executions if Defendants' execution procedure presents a substantial risk of serious harm, in violation of the Eighth and Fourteenth Amendments to the United States Constitution.
- 213. Mr. Loden also possesses a right under the First and Fourteenth Amendments to the United States Constitution and Article 3, Section 24 of the Mississippi Constitution to have a reasonable opportunity to present legal claims implicating fundamental constitutional rights to the courts.

- 214. Defendants' policy of secrecy prevents Mr. Loden from accessing all of the relevant information he needs to mount an Eighth Amendment challenge to Defendants' lethal injection protocol, and thus violates his right of access to the courts.
- 215. For the reasons set forth above, Defendants are deliberately indifferent to Mr. Loden's constitutional rights.
- 216. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count V.

#### PRAYER FOR RELIEF

WHEREFORE, Mr. Loden requests that this Court:

- 1. Grant a declaratory judgment that pentobarbital is not "an ultra-short acting barbiturate or other similar drug" and is therefore not permitted for lethal injection executions in Mississippi;
- 2. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden with pentobarbital, which is not an ultra-short acting barbiturate;
- 3. Grant a declaratory judgment that the words "in combination with a chemical paralytic agent" in Miss. Code Ann. §99-19-51 violate the Eighth and Fourteenth Amendment to the United States Constitution;
- 4. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden with compounded drugs;

- 5. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden with drugs that have passed their expiration date;
- 6. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden with a three-drug series which includes a chemical paralytic agent and potassium chloride;
- 7. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden until such time as Defendants can demonstrate the integrity and legality of any and all controlled substances they intend to use for Mr. Loden's execution;
- 8. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden without providing full and complete information about the drugs that Defendants intend to use in their execution, within sufficient time for Mr. Loden to raise any statutory or constitutional challenges to the use of said drugs.
- 9. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden until such time as Defendants can demonstrate that measures are in place to allow for Mr. Loden's execution in a manner that

complies with the Eighth and Fourteenth Amendments to the United States Constitution;

- 10. Award costs and attorney's fees pursuant to 42 U.S.C. §1988; and
- 11. Grant any such other relief that this Court determines to be just and proper in these premises.

Respectfully submitted, THOMAS EDWIN LODEN, Jr.

By: /s/ Stacy Ferraro

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Counsel for Intervenor Thomas Edwin Loden, Jr.

#### **CERTIFICATE OF SERVICE**

I hereby certify that I have filed this pleading with the Electronic Case Filing System of the United States District Court for the Southern District of Mississippi, and have thereby served counsel of record for the Defendants and the Intervenors in this case.

This, the 12th day of June 2020.

/s/ Stacy Ferraro

Stacy Ferraro